Food·Drug·Cosmetic Law

The editorial policy of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need.

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FOOD DRUG COSMETIC LAW JOURNAL

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About the Authors

Following his graduation from the Ontario Agricultural College, University of Toronto, **G. L. Kalbfleisch** worked for Baxter Laboratories of Canada as a chemist—and later as chief chemist—from 1943 to 1947. He returned to the university as a research assistant studying pyrogens, and received an M. S. A. degree in pharmacology in 1948. Following employment as pharmaceutical representative for Ingram and Bell, Ltd. of Toronto, he went to the Food and Drug Directorate to work in the inspection services. In 1952, he became the directorate's technical secretary, and he has since handled technical correspondence and special projects for the director.

One such project was the organization and direction of the drug-inspection program, on which Mr. Kalbfleisch bases his article in this December JOURNAL. The program, which includes training of inspectors, is now almost a full-time job with him, but he also serves as secretary of the Canadian Drug Advisory Committee.

Bradshaw Mintener was Assistant Secretary of the United States Department of Health, Education, and Welfare for over two years, until his recent resignation to take up the practice of law in Washington, D. C.

Before his government appointment, Mr. Mintener had been associated with Pillsbury Mills, Inc., at Minneapolis, since 1933. He served as Pillsbury's assistant general counsel and assistant secretary, and in 1935 became its vice president and general counsel.

L. B. Jensen received his doctorate from the University of Chicago in 1927 while he was an instructor there. He joined Swift & Company as chief bacteriologist in 1931 and has also served since 1942 as a lecturer in the veterinary meat and dairy hygiene school of the Army Medical Service, at Chicago. In 1953, he was appointed by the United States Surgeon General as consultant in the field of microbiology of foods and bacterial food poisoning, Walter Reed Army Institute of Research, Washington, D. C. He has also been an assistant professor at Mayo Foundation of the University of Minnesota and first assistant in the department of experimental bacteriology at Mayo Clinic, Rochester, Minnesota.

"Significant Comments," written by **Thomas W. Christopher,** also appears in this issue. Mr. Christopher is associate dean and professor of law at Emory University, at Atlanta, Georgia.

In the Food and Drug Administration

Monthly Report, Issued November 29.—Contaminated foods seized in 57 federal court actions in October totaled 1,467 tons, the Food and Drug Administration reported in its monthly summary. This compares with a monthly average of 283 tons for the 1956 fiscal year. One unusually large seizure during October consisted of 2⅓ million pounds of unprocessed chocolate that had become insect-infested during storage.

In addition to foods removed from consumer channels by seizure, 170 tons were voluntarily destroyed or brought into compliance by the owners. Three firms made extensive plant and equipment improvements, and adopted better control procedures as a result of FDA inspectors' reports to management on conditions they observed. Another firm has moved into a new plant costing $200,000, following a 1955 court action based on lack of adequate sanitary controls.

Fourteen drug and device shipments were seized during the same period for alleged violation of the Federal Food, Drug, and Cosmetic Act. One consisted of four tons of low-grade, crushed radioactive ore in a "uranium health center." The ore, placed in eight boxes on which patients lay for treatments for bursitis, arthritis or rheumatism, had low radioactivity, according to FDA tests, and had no therapeutic value. One seizure involved repackaging and relabeling of new drugs by a wholesaler without an effective new-drug application permitting such operations.

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Journal

Some Legal and Practical Aspects

OF DRUG-PLANT INSPECTION IN CANADA

By G. L. KALBFLEISCH

Early in Its New Inspection Program, Canada's Food and Drug Directorate Thoroughly Surveyed the Drug Industry and Inaugurated a Rating System for Firms. Mr. Kalbfleisch Reports on the First Two Years of the Program

IT IS APPROPRIATE to report on this subject because we have just completed our second year of effort in this sphere. We do not have the backlog of experience in drug-plant inspection which our American counterparts possess, since clear-cut authority for drug-plant inspection and examination of records in this country was provided only in the Food and Drugs Act, 1953, which was proclaimed on July 1, 1954. However, starting late with some time for advanced planning may have advantages, since we have been able to draw on the experience of others and adapt this knowledge to our own purpose.

There were, of course, under the previously existing legislation, provisions for the licensing of firms which manufactured what may be broadly described as the biological, injectable drugs. Plant inspection was a part of this licensing system from the beginning and has continued, under the new act, to be rigidly enforced, with very high standards, in view of the nature of the products.

The Author, Technical Secretary to the Canadian Food and Drug Director, Has Handled the Organization and Direction of the Drug-Plant Inspection Program

Unsanitary Conditions

Section 8 of the Food and Drugs Act, 1953, reads as follows:

No person shall sell any drug that

(a) was manufactured, prepared, preserved, packed or stored under unsanitary conditions; or

(b) is adulterated.

In addition, Section 11 makes it an offense to manufacture, prepare, preserve, package or store for sale any drug under unsanitary conditions. It is clear, therefore, that a charge could be laid on the basis of observed unsanitary conditions in drug plants. This has not been done to date, but in a few cases unsanitary conditions or poor housekeeping have been brought to the attention of the management for correction, with good results. Since the materials used in the manufacture of drugs are not likely to support insect or bacterial growth and because of the generally more informed personnel in drug plants, conditions which could be described as unsanitary, to the satisfaction of a court, are relatively scarce. The possible large exception to this general observation is the conditions in establishments in which injectable preparations are manufactured.

Legal Authority

Drug-plant inspectors must operate within the authority provided in Sections 21 ("Powers of Inspectors"), 22 ("Forfeiture") and 23 ("Analysis") of the act, which are reprinted below:

21. (1) An inspector may at any reasonable time

(a) enter any place where on reasonable grounds he believes any article to which this Act or the regulations apply is manufactured, prepared, preserved,

packaged or stored, examine any such article and take samples thereof, and examine anything that he reasonably believes is used or capable of being used for such manufacture, preparation, preservation, packaging or storing;

(b) open and examine any receptacle or package that on reasonable grounds he believes contains any article to which this Act or the regulations apply;

(c) examine any books, documents or other records found in any place mentioned in paragraph (a) that on reasonable grounds he believes contain any information relevant to the enforcement of this Act with respect to any article to which this Act or the regulations apply and make copies thereof or extracts therefrom; and

(d) seize and detain for such times as may be necessary any article by means of or in relation to which he reasonably believes any provision of this Act or the regulations have been violated.

(2) For the purposes of subsection (1), the expression "article to which this Act or the regulations apply" includes

(a) any food, drug, cosmetic or device,

(b) anything used for the manufacture, preparation, preservation, packaging or storing thereof, and

(c) any labelling or advertising material.

(3) An inspector shall be furnished with a prescribed certificate of designation and on entering any place pursuant to subsection (1) shall if so required produce the certificate to the person in charge thereof.

(4) The owner or person in charge of a place entered by an inspector pursuant to subsection (1) and every person found therein shall give the inspector all reasonable assistance in his power and furnish him with such information as he may reasonably require.

(5) No person shall obstruct an inspector in the carrying out of his duties under this Act or the regulations.

(6) No person shall knowingly make any false or misleading statement either verbally or in writing to any inspector engaged in carrying out his duties under this Act or the regulations.

(7) No person shall remove, alter or interfere in any way with any article seized under this Act without the authority of an inspector.

(8) Any article seized under this Act may at the option of an inspector be kept or stored in the building or place where it was seized or may at the direction of an inspector be removed to any other proper place.

22. (1) An inspector shall release any article seized by him under this Act when he is satisfied that all the provisions of this Act and the regulations with respect thereto have been complied with.

(2) Where an inspector has seized an article under this Act and the owner thereof or the person in whose possession the article was at the time of seizure consents to the destruction thereof, the article is thereupon forfeited to Her Majesty and may be destroyed or otherwise disposed of as the Minister may direct.

(3) Where a person has been convicted of a violation of this Act or the regulations, the court or judge may order that any article by means of or in relation to which the offence was committed or anything of a similar nature belonging to or in the possession of the accused or found with such article, be forfeited, and upon such order being made, such articles and things are forfeited to Her Majesty and may be disposed of as the Minister may direct.

(4) Without prejudice to the operation of subsection (3), a judge of a superior, county or district court of the province in which any article was seized under this Act may, on the application of an inspector and on such notice to such persons as the judge directs, order that the article and anything of a similar nature found therewith be forfeited to Her Majesty to be disposed of as the Minister may direct, if the judge finds, after making such inquiry as he considers necessary, that the article is one by means of or in relation to which any of the provisions of this Act or the regulations were violated.

23. (1) An inspector may submit any article seized by him or any sample therefrom or any sample taken by him to an analyst for analysis or examination.

(2) Where an analyst has made an anaylsis or examination he may issue a certificate or report setting forth the results of his examination or analysis.

On reading the above sections of the act, it will become evident that the authority of inspectors in drug plants—notably, the power of seizure—is very broad and must be used with discretion. Seizure is probably the main tool of enforcement in Canada. It is not taken lightly and it is not abused. Also, it may be of particular interest to non-Canadians to mention at this time that there is no jurisdictional dispute on the application of these provisions of the act as they apply to drug-plant inspection and that food and drug inspectors' authority is unquestioned, regardless of provincial boundaries.

Progress Report

The Honorable Paul Martin was able to make the following report in the House of Commons debates for May 14, 1956 (page 3889) in reply to a question by Mr. Houck on the progress in implementing the drug-plant inspection clauses of the Food and Drugs Act:

Following proclamation of the Food and Drugs Act on July 1, 1954, a complete survey of the drug manufacturing industry was undertaken by the Food and Drug Directorate of the Department of National Health and Welfare. This survey was completed in 1954-55, more than 350 preliminary inspections having been made. The pharmaceutical industry in Canada is relatively small, but there is great variety in the products, the size of the companies and their production and distribution facilities. Of principal importance in drug firms is the existence of a record control system which enables the manufacturer to trace his products in the course of manufacture and to check on the raw material used in his products.

As a result of the preliminary survey and because of the limitation in number of staff available for the work, priorities were established. Particular attention was given in 1955-56 to private formula manufacturers, manufacturers of injectable drugs and drug manufacturers in general, as distinguished from distributors and wholesalers. Fewer inspections—253—were carried out in 1955-56 but on each inspection more time was spent making recommendations, and repeat visits were made to a number of establishments.

Progress has been noted in many cases, particularly among some of the smaller manufacturers who were not aware that their manufacturing procedures and record systems did not constitute good commercial practice. With particular

reference to injectable drugs, a number of manufacturers agreed voluntarily to discontinue manufacture of these products when it was pointed out that their facilities were inadequate to ensure complete safety of the products.

Modus Operandi

It might be of interest to elaborate on the method of operation used in drug-plant inspection at this stage of our development in Canada. As indicated, we did a thorough survey of the pharmaceutical industry in the early stages of our program and a system of rating firms was inaugurated. So many factors enter into the assessment of individual firms that a numerical rating must be taken with a grain of salt. We are fully aware of this, and use these only as an indication of relative merit. In practice, the drug-plant inspector uses a check list which was devised with the collaboration of all those interested in this particular aspect of enforcement and which serves to ensure that the inspector will look into the most important points during his inspection. He is encouraged, as well, to provide a short written report on each firm. The main advantage in a confidential rating on each firm is that they may be divided into groups. For example, at present, we rate firms numerically from one to nine. Those rated one to three receive an annual visit or inspection, those rated four to six receive two inspections per year and those rated seven to nine receive three or more inspections per year. On the repeat inspections, a different report form is used, which simply deals with the recommendations made on the previous visit and the progress noted on subsequent inspections.

The function of the drug inspector on these inspections is to try to locate weak points in the control systems in drug plants which would allow for mistakes in manufacture. In many cases, it was not very difficult to find these weaknesses, since control systems were practically nonexistent. In such cases, the inspectors are expected to suggest a practical basis for a control system which can be improved as the manufacturer shows his capability to expand the system. This is largely an educational program, and its value has been demonstrated. Analytical control can only detect errors which have been made in the samples which are analyzed. This is valuable information, but a great many mistakes would never happen if reasonable precautions are taken and there is an adequate record control system in the plant. For example, we stress the checking of raw materials, the identification of raw materials in storage and the dispensing of raw materials against a work order or production sheet. It is not generally

understood in industry—particularly among the small manufacturers —that the work order or production sheet corresponds to a prescription and that the ingredients must be dispensed by a responsible person against this work order in the same way that a pharmacist compounds a prescription. In addition, it is stressed that all lots or batches in process must be identified in all manufacturing processes. White powders, for example, all look disturbingly similar when they are sitting around in containers. These are cardinal rules, and there are many others, such as the designation of responsible staff to issue labels and supervise the labeling operation. The control laboratory in the plant exists to make sure that all of the other staff members have done their jobs properly, and it is no substitute for the precautions which are outlined above.

Drug inspectors are requested continually to reassess the regulations under which they operate. As they gain more experience and enforce these regulations, it does become evident that some regulations are not strict enough, and that others may be more strict than necessary, for the protection of the public. One of the results of drug-plant inspection is that the regulations have been amended to require a lot number to appear on all labels for drug products for internal use. A lot number is defined in Section A.01.010(f) as meaning any combination of letters, figures, or both, by which any food or drug can be traced in manufacture and identified in distribution. Indirectly, therefore, this requirement of a lot number on labels also requires the maintenance of control records.

Since July 1, 1954, we have designated certain of our staff for drug-plant inspection work. These men have been given training in this specialized field and meet to discuss the problems encountered. It is our feeling that if this program is to succeed to the satisfaction of industry and ourselves, these men must know a great deal about the pharmaceutical industry. It is not sufficient simply to point out that something is wrong. If they are to perform their full duty to the Canadian public, they must be in a position to make definite recommendations which can be carried out by the manufacturer to make his operation safe. If the operation is such that he cannot do this, then his obligation to the public is to seize stocks of the drugs or apply other sanctions. It is not expected that any manufacturer will change his whole method of operation overnight, but it is expected that he will show progress on the recommendations made.

A great deal of information is included on our inspection forms which can be tabulated in our head office to provide a very good picture of the drug industry in Canada. This also is a function of drug-plant inspection. In order to make recommendations for corrections, we must know the whole field so that all manufacturers are treated fairly and there is no discrimination. The program which has been laid out in Canada is simply this: Know the industry, assess the industry, attack the worst problems first, and do this evenly across the board.

Purposes of Drug-Plant Inspection

The main purpose of drug-plant inspection is to promote good manufacturing practice in the industry in order to ensure that drugs are produced in an acceptable manner to protect public health. As indicated, this involves reducing preventable mistakes to a minimum by the use of a good record system and trained personnel in drug plants. These must ensure against substitution of dangerous ingredients and that safeguards are present to detect any mistakes which may be made.

The role of the drug-plant inspector in this regard is reminiscent of the homely adage made famous by President Teddy Roosevelt: "Speak softly, and carry a big stick; you will go far." The drug-plant inspector is trained to do just this, and his first duty is to obtain cooperation. However, the threat of seizure which is always in the background and recognized by industry is a big stick.

Results

Possibly it is too early to judge the success of the drug-plant inspection program, but conditions in many pharmaceutical plants in Canada have improved. This has become evident in a number of unexpected ways. Our regional directors have on file letters from some manufacturers thanking us for inspecting their premises and for suggesting improvements. The improvements which are suggested do not always cost money. In fact, in a number of cases, the reverse has been true and the inspector has been able to point out a much simpler way to accomplish the same purpose. He has also demonstrated that the records which we require are also to the advantage of the manufacturer in that he knows his sources of raw materials much better. In many cases, the inspector has simply recommended that the housekeeping and storage facilities should be improved and, on the next

visit, the manufacturer is extremely proud of the results, and admits that his working efficiently is increased. Probably the most unexpected result which has come to our attention and which is a good testimony for the effectiveness of the drug-plant inspection program, is the unsolicited statement by one of our larger manufacturers to the effect that he has lost an appreciable number of his trained staff to the smaller firms who are now setting up control systems. He was not overjoyed at the prospect of training new staff members but, at the same time, he realized that this was for the good of the industry in that it tends to eliminate unfair competition. **[The End]**

• FAIR TRADE IN THE COURTS—1956 •

During 1956, the courts of last resort of five states—states having 6.4 per cent of the population of the United States—declared fair-trade laws of those jurisdictions to be wholly or partially unconstitutional, according to a year-end summary by John W. Dargavel, chairman of the Bureau of Education on Fair Trade. During the same period, three state courts of last resort upheld the constitutionality of their state fair-trade laws.

The top state courts which rendered their state fair-trade laws ineffective were those of Colorado, Louisiana, Oregon, Utah and Virginia. In the first three of the named states, only the nonsigner clauses of the state fair-trade laws were held to be unconstitutional. Utah's supreme court ruled the whole fair-trade act to be in violation of the state constitution. In Virginia, the law was held to have been repealed by virtue of an amendment to the Virginia antitrust laws which was enacted after the fair-trade act.

California, Massachusetts and Maryland courts of last resort upheld the constitutionality of their state acts. In both Massachusetts and Maryland, the high courts held that state fair-trade laws did not violate the due-process clauses of their state constitutions nor involve an improper delegation of legislative power. Both tribunals stressed the importance of the courts' accepting the judgment of legislatures with respect to economic facts.

As of the time of Dr. Dargavel's report—released December 12—the score on constitutionality—in whole or in part—of fair trade in state courts of last resort stood at 16 for and ten against, with test cases pending in Arizona, Indiana, Kentucky, Ohio and South Carolina.

In federal courts of appeal, fair trade was sustained on three occasions. However, none of these cases involved issues of constitutionality.

The United States Supreme Court did not rule on the constitionality of fair trade during 1956. Thus, the landmark decisions upholding state fair-trade acts and the federal McGuire Act were left intact.

The Food-Additive Problem

By BRADSHAW MINTENER

The Author—Addressing Divisions of Agricultural and Food Chemistry and of Chemical Marketing and Economics, American Chemical Society, at Atlantic City September 17—Expressed Belief That Government and Industry Will Work Out This Complicated Problem in a Mutually Satisfactory Way

MR. CHAIRMAN, Ladies and Gentlemen:

When I accepted the invitation to be your speaker I was in the odd position of not being able to tell your chairman how I should be introduced—as a government official, or as plain Brad Mintener, attorney at law in Washington, D. C. Tonight I am still, for the moment, wearing my GI hat, and able to bring you an official message from the Department of Health, Education, and Welfare.

I suspect all of you know that this year is the fiftieth anniversary of the original pure Food and Drugs Act of 1906. The man who fought for this law, and finally secured its enactment after a 25-year struggle, was one of the great presidents of the American Chemical Society. You may have seen his portrait recently on a United States postage stamp—the only one of your past presidents to have been so honored.

Harvey W. Wiley was president of the American Chemical Society from 1893 to 1894. As Chief of the Bureau of Chemistry of the United States Department of Agriculture, he was at that time engaged in the analytical research work on food adulteration which documented his case for a federal statute. His chemists in the bureau were testing thousands of samples for the presence of the various chemical preservatives—some of them toxic—which were then extensively used. Wiley was gathering the facts, as they were then understood, which he later set before the public and the Congress.

The journalism of that time tended to picture Dr. Wiley as a crusader and a zealot. Dr. Wiley himself says in his biography that

At the Time of This Speech, Mr. Mintener Was Serving as Assistant Secretary, Department of Health, Education, and Welfare

the pure food advocates were commonly looked upon as "cranks and reformers without much business sense."

Today we can distinguish between Dr. Wiley the legendary reformer and Dr. Wiley the man. Dr. Wiley made his mistakes, but his life and writings amply contradict the impression that he was a Don Quixote. He was indeed an exceptionally able man, with many achievements in addition to the pure food law. Among these were his career as a distinguished teacher of chemistry and his many contributions in the chemistry of sugar. The latter made him the father of the American beet sugar industry, as well as of our pure food law.

Busy as he was, Dr. Wiley found time to be a very active member of the American Chemical Society. My friend Walter Murphy tells me that he is considered one of those who were instrumental in establishing the society on a national basis, and that without his effective services the society might not have survived nor reached its present eminence as the voice of the chemical profession, with nearly 80,000 members.

Your journal, *Chemical and Engineering News,* recently paid tribute to this pioneer of chemistry and modern government, and I should like to quote from one paragraph of that tribute:

> In his lifetime Harvey Wiley was called many things—idiot, charlatan, visionary. In derogatory vein the New York *Sun* referred to him as "the chief janitor and policeman of the people's insides." But the title Wiley liked best is the simple phrase, engraved by his request on his headstone in Arlington Cemetery—"Father of the Pure Food Law."

The battle for the little six-page 1906 pure food law was a long and bitter one. It marked a fundamental change in public thinking

about the responsibilities of the federal government. People at first were unaware of the shocking conditions and problems which existed in some industries and plants. They did not realize the implications of the industrial revolution which was then going on in the mass production and interstate distribution of foods. When these things were brought out into the open and understood, the Wiley Act became law.

Today we have a somewhat similar situation in regard to the problem of chemical food additives. Fortunately there has been no such violent public controversy over this problem as there was in the pre-1906 era. But we have a problem, and it has taken time to acquire an understanding of the nature of that problem.

Law Governing Additives Merely a Punitive One

We can sum it up in this way: Advances in food chemistry and food technology have brought about a tremendous increase in the use of various kinds of additives, but there is no law which requires that these be tested and found safe to the consumer before they are put on the market. The law is not preventive—it is merely punitive, imposing penalties on the use of those additives which have been proved to be harmful. In very many cases it is difficult, if not impossible, to secure such proof. Additives of questionable safety may continue to be used, since evidence is lacking of any harmfulness. The backlog of research needed to establish safety of all these materials has grown to the point where it far exceeds the resources and scientific personnel of any government agency. In fact, a recent report on the FDA research program on coal-tar colors says that it would take 25 years for the present staff to complete the studies which should now be undertaken in that one field.

This is indeed a big problem. Since 1940 it is estimated that about 25,000 new chemical substances have been screened by industry's research laboratories for possible utilization as food additives. The Administration estimates that around 400 chemical substances are today being used for various purposes in food production. This is a conservative estimate—the Food Protection Committee of the National Research Council has published a list of about 500 of these additives. The FDA people break their figure down into three categories. They classify about 150 as harmless—that is, inert or innocuous. Another 100 are considered as safe within the limits of use—that is, in the quantities in which they are normally used. The remaining 150 are in a scientific no man's land—they are in use but have not been

adequately tested. Administration scientists do not know whether they are safe or not, but they suspect that some of them ought not to be in use.

I might point out in this connection that the figures I have just given you are FDA's up-to-date estimates—they are not the figures that appeared in the Delaney Committee report and, of course, they do not include the pesticides which have been taken care of under the new pesticide law.

Recent Congressional Bills

Eleven bills were introduced in the last Congress to require the testing of new chemical additives for safety before they are put into foods. Hearings were held by the House Committee on Interstate and Foreign Commerce, and I would say that those hearings covered the subject very completely. As I told the American Bar Association recently, I do not share the belief that no progress was made on this important health problem during the last session of Congress. It is unfortunate, I feel, that the hearings took a course which eventually resulted in a stalemate. However, these hearings did bring out the differences between the various bills. They also showed that there was a wide area of agreement as to the objectives which should be attained. Finally, the points of controversy were quite clearly defined, making it possible to focus attention on resolving those differences in a law that will be adequate to protect the public.

This whole question of chemical ingredients in food, in my opinion, is one of the most serious public-relations problems of the food and chemical industries. That is so because the problem is fundamentally a public-health matter—one that is of interest and concern to every country in the world. These chemical materials have become essential to the world food supply. Some of them, such as the vitamins, are indispensable to life and health. But the fact remains that others are potentially harmful.

International Cancer Symposium

My attention has been called to the recent news reports on the symposium of the International Union Against Cancer, which was held in Rome last month. Some of the statements in those reports were quite alarming. Without commenting on their scientific accuracy, I believe there are several points in connection with the Rome meeting which ought to be made crystal clear to everybody.

First of all, the United States Food and Drug Administration is on record that it does not know of any food additive presently used in the United States that causes cancer. If it had any evidence of such, it could and would take immediate action under the existing law to stop the use of such a chemical. The Administration continues to regard the American food supply as the best and safest in the world, and these FDA scientists, having had more experience with this matter of chemical additives than those of almost any other country, should know what they are talking about. Considering their limited resources, both financial and legal, they have done a magnificent job.

Second, it should be made clear that the American food and chemical industries have cooperated voluntarily to protect the public and, without compulsion by any law, have done a vast amount of scientific research to insure unquestioned safety of the majority of the additives now used. Furthermore, these industries are on record in support of legislation to make mandatory the present voluntary clearance program.

Third, the Rome reports have again made clear the fact that there are chemicals in use in food today which have not been studied sufficiently to make sure that they do not cause cancer, as well as being safe in other respects. When scientists of 19 leading countries of the world unanimously reach such a conclusion and recommend a course of action for all the world to consider, we can hardly expect the problem to disappear by itself, nor can we expect the press and public to take no interest in such a problem. Of course, there will be instances of exaggeration, misunderstanding and misapprehension. That is what always happens when people are hearing about a complex scientific problem for the first time. So we have a public-relations problem, a scientific problem and a public-health problem on our hands, all rolled up together, and do not think this is not a headache to the government—FDA—as well as to you people in industry.

I think it is obvious that this problem will never be solved satisfactorily as long as there is any question or doubt that all food ingredients are not as completely safe as it is humanly possible to make them. The only solution, in my opinion, is a law that requires adequate testing, and there should be no loopholes in this requirement. The basic bills which were considered by the House committee will no doubt be reintroduced in the new Congress. Others may be offered. We will have to try again to secure agreement on a law which will protect the public and also protect the legitimate rights of industry.

One of the problems which we will have to deal with is the so-called grandfather clause to exempt from the testing requirements additives which for a long time have been and are now in use. There is no doubt that some kind of grandfather clause is necessary to exempt those additives which are generally known to be safe. It would be unnecessary and a hardship to require elaborate scientific tests to be conducted or repeated on such chemicals as vitamins, for example, on which we already have extensive pharmacological data.

The department went on record, however, as being opposed to any form of grandfather clause which would have the effect of exempting from the testing requirements chemicals which have not previously received the approval of FDA or which are not generally recognized by competent, expert authorities as safe for their intended use. Obviously, this is the only position which the government can take without being derelict in its duty to protect the public.

History of Law

Since 1906, the federal pure food law has been concerned with the addition of "poisonous and deleterious" substances to food. Originally, the law prohibited additives which "may" by any possibility injure any consumer. In 1938, Congress attempted to strengthen the law to prohibit added poisonous or deleterious substances regardless of amount. It exempted only pesticides and other chemical poisons which are necessary or cannot be avoided in the production of food. This is the famous "per-se" rule. Recently, the Miller Amendment has provided an improved procedure for fixing safe tolerances for the residues of pesticides.

At hearings in the last Congress, Commissioner Larrick testified that FDA is willing to have this tolerance principle extended to food additives generally. This was a far-reaching step. It means abandonment of the per-se rule and would be a modification of the "necessity" rule. It would mean that any chemical additive—even a known poison—could be used in a harmless amount, provided it would serve some useful purpose in production or be of benefit to the consumer. In my opinion, this is a scientifically sound position. It has been endorsed by a number of scientific bodies. Many food components, naturally present as well as added, are poisons in large amounts but are beneficial in small amounts. Some, indeed, are essential to nutrition.

If safe tolerances can be established for pesticides, they can certainly be established for other food additives. The per-se rule was

never a scientific one in my judgment, and mainly on that account it has often been impractical of enforcement. To abandon it, we feel, is a realistic step. Nevertheless, it is a far-reaching step. The food and chemical industries, through millions of dollars spent in research, have made great technical progress under the per-se rule. They have been able to develop and use a large number of nontoxic additives. Now we are ready to have the door opened to a large increase in the number of possible additives, including some which would be harmful unless used in carefully controlled amounts. But is it unreasonable to require that when a toxic material is being added to the Nation's food it should serve some truly useful purpose? Let us remember we are not dealing merely with a wider marketing opportunity for chemical compounds.

The pharmacologists tell us that because their tests are conducted largely with laboratory animals it is not possible to determine with complete certainty that chemical additives will be harmless to man. There is always a residual risk in permitting use of even small quantities of poisons in foods to be consumed by the young, the old, the sick, and the well. The Department believes it should be able to consider all the facts—of usefulness as well as toxicity—when making the important decision whether to allow a toxic material in the Nation's food supply. When the material is not toxic, we are willing to waive the criterion of utility.

Court-Review Procedure

There is one more controversial issue on this chemical-additive legislation. That is the question of procedure in regard to court review.

The issue which has been raised is one that has concerned me, as a lawyer, for many years. It is the old question of the complete fairness of the so-called administrative process, under which the executive agency conducts a hearing, makes findings of fact, and issues an order, subject to review by the court of appeals on the question of whether the order is supported by substantial evidence and is not arbitrary, unreasonable or capricious.

No doubt you have all heard the basic criticism of this procedure, which is that the agency which determines the facts can control the decision because the court must find in favor of the government if there is any substantial evidence to support the findings. (Some people

argue about just how this should be stated, but I think my language is substantially correct.) I have always felt there is a basic question here, and with many other lawyers I feel that this is a part of the entire administrative process that deserves further study.

Nevertheless, I think it is very unfortunate that this chemical-additive legislation, which is a matter of public health and safety, should have been made a vehicle for experimentation to correct possible shortcomings of the Administrative Procedures Act. The fact is that this particular legislation provides a very weak platform for such an effort.

The administrative procedure was made to order to deal with such problems as this chemical-additive matter. If there were ever a situation which called for using the administrative process, in my opinion this is it.

The Department went on record as favoring the conventional type of court review, as set up in other sections of the Federal Food, Drug, and Cosmetic Act. We were opposed to the so-called declaratory-judgment feature in some of the bills. I am a lawyer, but I do not feel that the decision in such matters as this should be determined by such factors as which side has the cleverest or most convincing lawyer, yet that is what may frequently happen if these complex scientific questions may be taken out of the hands of the scientists and thrown into a courtroom for a trial *de novo*.

If there were in our judicial system a type of court specializing in scientific cases, whose decisions would be binding throughout the country, I would feel that would be a better solution. The trouble is we do not have such a court, and we have 251 federal district court judges in 91 districts, all over the country, each of whom could give a different answer. Furthermore, under the proposed declaratory-judgment procedure, the government would have to go into court on short notice and try to prove that its decision about the adequacy of the scientific research was correct. This would involve proving that the additive might be harmful, and the burden of proof would be on the government, just as it is under the present law. If the government did not go to court, the firm could go ahead and market the additive. It would leave us, it seems to me, with about the same inadequate legal protection that we have today. Pretesting would be required, but anybody who wanted to get away with an incomplete pretesting job would be in a good position to do so.

I believe that the scientific question as to whether an additive has been shown to be safe for consumers should be decided initially by qualified scientists. Any doubt should be resolved in favor of the consumer.

Finding Solution to Problem

But I am not discouraged about the prospects for this essential legislation. It is too greatly needed. Consumers and industry alike need the protection which mandatory pretesting will provide. Many leaders of the food and chemical industries are well aware of the situation which now exists and have worked hard to develop a solution to the problem. I think these public-spirited men in the industry and in Congress should be commended for their sincere efforts to devise acceptable and effective legislation on this problem.

I am sure that we will work out this important and complicated problem in a mutually satisfactory way—in the American way of give and take. I urge all of you men to interest and inform yourselves in this problem and help us to solve it. If people in government and industry cannot solve this problem together cooperatively, in my opinion it will not be done for the benefit and greatest good of the greatest number of people.

Let us "let bygones be bygones" and start afresh by sitting around the table of discussion, understanding and statesmanship, and work out this all-important problem of chemical additives which is so vital to the American consuming public and American industry. We can, and I am sure we will, find a solution.

Now I should like to make a few personal observations. This great chemical industry is not only one of the largest, but it is one of the most important in the United States. Chemistry, during the last two or three decades, has revolutionized our mode of living. You have made significant, vital and far-reaching contributions to our American way of life. This tremendous development and progress carries with it, it seems to me, a grave responsibility to devote your initiative, your scientific know-how, your brain power and your leadership to preserving our democratic way of life in all of its aspects.

I am grateful to President Eisenhower for having given me the opportunity to serve in the federal government under his leadership. These past years have been two of the most rewarding and educational in my whole life. I am proud to have been a member of the Eisenhower team.

I am grateful to Mrs. Hobby, the first Secretary of our Department of Health, Education, and Welfare, the first new cabinet department created in more than 40 years, for having given me the privilege of working so closely with FDA. We are very fortunate to have had Mrs. Hobby as our first Secretary because she is, in my opinion, one of the outstanding American women of our generation. Her successor, Mr. Folsom, came to us at a very opportune time, and is one of the outstanding leaders of American industry. With his broad and varied experience through the years—working closely with the federal government in many of its operations—together with his deep humanitarian interests, he has given us outstanding leadership during the year that he has been the head of our Department.

I have worked with people all of my life but have never worked with a more dedicated, competent, fair-minded, experienced and conscientious group of men and women than those who comprise our FDA. As long as the responsibility for protecting the food, drug and cosmetic supply of our Nation is in the hands of people like Commissioner George P. Larrick and his associates, and if they are given adequate facilities and resources to carry out their responsibilities, together with the continued cooperation of the regulated industries, I am sure that our foods, drugs and cosmetics will continue to be the best in the world.

I pledge myself to work for continued, effective cooperation between government and industry, of which your chemical industry is so vital a part, to the end that the health and welfare of our Nation will continue to prosper. **[The End]**

• FOOD—BROKERAGE COMMISSIONS, MISREPRESENTATION •

Fruit products . . . A cooperative which sells the produce of Florida fruit packers is prohibited from paying brokerage, in violation of the Robinson-Patman Act, to firms buying fruit produce for their own accounts. According to an accompanying opinion, the firms—so-called brokers—treated the shipments as their own property, sometimes storing produce in their own warehouses and paying insurance on such produce. They sold the produce to persons, and under conditions of sale, unknown to the cooperative. (Issued November 26; released December 5, 1956.)

Health food . . . A company selling untreated alfalfa seed and vitamin tablets is prohibited from representing that its products have any therapeutic value in the treatment of arthritis. (Released November 28, 1956.)—CCH TRADE REGULATION REPORTS ¶ 26,290; 26,283.)

A SUMMARY OF

BACTERIAL FOOD POISONING

By L. B. JENSEN

Once a Food Has Passed Official Inspection, Further History Is Determined by (1) Perishable Character, (2) Microbic Content or Inoculation and (3) Time and Temperatures at Which It Is Held, Says Dr. Jensen, Chief Bacteriologist for Swift & Company, Chicago. He Offers Three Important Rules for Keeping Foods Safe

IT IS COMMON KNOWLEDGE that veterinary science exerts a far-reaching influence on the welfare of man. There have been many by-products of veterinary science. In this connection it is interesting to recall the development of the synchronized, meat-inspection chain, and the extension of this idea to the assembly line of production of tanks, automobiles, airplanes, and other implements of war and peace—the key to mass production.

The ultimate objective of our scientific work in production, preservation and judgment of foodstuffs of animal origin is to safeguard the consumer. It may not be presumptuous to state that there is theoretical, and enough factual, knowledge at hand to safeguard food supplies right up to the mouth of the consumer. The application of this knowledge, however, presents certain difficulties from the viewpoints of the veterinarian and bacteriologist on the production line, in the field and in the military camp. All appreciate the invaluable services of the federal, state and municipal meat-inspection services, and the Army Veterinary Medical Corps. When a food has passed official inspection, its subsequent history is determined by its perishable character, the microbic content or inoculation, and the time and temperatures at which it is held. The whole problem of food preservation and the prevention of the common type of bacterial food poisoning hinges upon these factors.

Most micro-organisms which may contaminate foods are harmless saprophytes so far as human health is concerned, but there are four genera of bacteria having species which can cause food poisoning. These bacteria are the staphylococci, salmonellae, streptococci, and *Clostridium botulinum*. A miscellany of bacterial species of uncertain role in food poisoning are *Cl. perfringens*, Proteus species, and *B. cereus*, which will not be further considered here.

Staphylococcus Food Poisoning

The identification of staphylococci as food-poisoning types cannot be made by ordinary laboratory methods. There are several biochemical types of these bacteria, but their classification has been made chiefly from their chromogenic properties, that is, the colored pigments (or lack of pigment) formed on laboratory media. Only a very few strains of staphylococci (phage group III) are capable of forming enterotoxin under suitable conditions. These strains can play a role in food poisoning by growing in a suitable medium under definite temperatures for known periods of time. Many nonacid foods containing over 30 per cent of moisture can support growth (and toxin formation) of food-poisoning bacteria. When staphylococcal cells alone are ingested (as they are in large numbers every day) by man or animals, food poisoning does not result. In aqueous media, these bacteria are killed at pasteurizing temperatures (143° F. for 30 minutes, 160° F. to 161° F. for 15 seconds) recommended by the United States Public Health Service (Bulletin 220) in the milk ordinance and code.

Staphylococcus aureus,[1] the golden or yellow-pigmented strain, is the usual kind of these bacteria implicated in food poisoning, although not all strains of this type can form enterotoxin. *Staphylococcus albus*, the variety which does not form pigment, has been implicated very infrequently in food poisoning although Dr. M. A. Barber [2] proved that the white staphylococci can cause food poisoning. Staphylococci are omnipresent in nature. They are carried in the nose and throat; postnasal "drip" or discharge and expelled sprays from coughing and sneezing ordinarily contain staphylococci. Pimples, carbuncles, boils, sores and infected cuts on fingers and arms, unpasteurized milk (from cows with mastitis), soil, and dust in all kinds of rooms may harbor these bacteria. In rooms controlled by technical sanitation methods—that is, controlled air or wet walls and floors where dust does not

[1] Renamed by taxonomists *Micrococcus pyogenes*, variety *aureus*.

[2] 9 Philippine Jour. Sci. 515-519 (Sec. B) (1914).

form or disperse into the air—micro-organisms are infrequently present as shown by air sampling in aspiration devices and exposed culture plates and liquid media.

Potential food-poisoning varieties of staphylococci are identified in the laboratory, using the criteria of Dr. G. M. Dack,[3] whose work in 1930 opened up the "modern era" in this field by proving the toxic nature of some staphylococci, and the epidemiology, symptomology, diagnosis and treatment.

Isolations of staphylococci are made on replicate nutrient agar and blood agar plates incubated at 95° F. for 48 hours, and additionally at 75° F. for two to four days. Chromogenesis of many strains on the nutrient agar plates is enhanced at 75° F. There are also selective media containing tellurite, mannitol, salt, etc., which may be used in analysis of samples overgrown with other bacteria. A tentatively positive sample ordinarily shows large numbers of staphylococci, but a heated or cooked sample of food may not harbor viable cells. Dead coccal cells are enumerated by direct microscopical examinations of strained smears of the emulsified food. The cells do not disintegrate when cooked or heated as in canning procedures. In case of enterotoxin formation in a suitable substrate, the cocci are present in large numbers. Five to ten or more colonies are picked and transferred to agar slants for stock cultures, to nutrient broth for coagulase tests, and to a special semisolid agar medium in flasks incubated in 15 per cent to 20 per cent carbon dioxide gas to be used in monkey feeding tests. Many of the colonies are hemolytic on blood agar, but hemolysis provides no certain identifying characteristics in respect to enterotoxin formation by the strain. Coagulase "positive" strains—that is, the power of a 24-hour broth culture to coagulate citrated whole blood or rabbit plasma—are frequently enterotoxin formers, but in our experience many coagulase positive strains are not enterotoxin food poisoners.

Man, and monkeys to a lesser extent, are susceptible to the action of enterotoxin by ingestion, but numerous animals which have been tested in this manner can ingest known toxic filtrates with impunity. Many laboratory workers acting as "human volunteers" have swallowed graded doses of enterotoxic filtrates, and the observers have obtained useful and precise data on symptoms, time of onset, time and temperatures necessary for toxin production, types of foods or media in which the toxin can form, susceptibility to the toxin, and

[3] *Food Poisoning* (The University of Chicago Press, 2d Ed., 1949).

treatment. Ordinarily, the volunteer cannot be talked into a repeat test. Rhesus monkeys are the best test animals because their reactions are similar to man's, although other species of monkeys can be used for demonstrating enterotoxin. The monkeys should first be tested for susceptibility to enterotoxin, and each sample should be fed in triplicate. Monkeys are less sensitive to enterotoxin than most humans.

From the foregoing it was established that a few humans and a few monkeys are not susceptible to staphylococcus enterotoxin, but the vast majority of people are made ill with characteristic symptoms. The time of onset is usually 2.5 to three hours, but the range is one hour to six hours in both man and monkeys, depending upon dosage and susceptibility. The symptoms are nausea, vomiting, cramping, retching and diarrhea. Body temperature may be subnormal.

Dr. C. E. Dolman,[4] the Canadian authority in this field, observed:

> The vomiting is accompanied, and sometimes replaced by, considerable retching. At first one is astonished to note what depths, and after what strivings, it is possible to recall portions of meals long forgotten . . . . The ordeal can perhaps be compared to pregnancy, in that it may have been light-heartedly enough embarked upon the first time, but is not so willingly repeated; and in its being made bearable, as the situation moves towards a climax, only in the reflection that deliverance is bound to come . . . . Once begun, recovery was usually rapid, the only after-effects being a large appetite, and a sense as of calm after a storm.

The time necessary for growth and toxin (enterotoxin) production of pure cultures of food-poisoning strains in a suitable medium is about five hours (four to six hours). Barber[5] found that five hours' incubation of inoculated milk at room temperature resulted in food poisoning when he drank the milk. The temperature range for toxin production is 60° F. to 115° F. with optima in the range 70° F. to 97° F., depending upon the characteristics of a strain.[6] Experiments have shown that toxin development does not take place below 60° F., and Segalove and Dack[7] found that enterotoxin is not formed in periods up to four weeks at 6.7° C. (44° F.) even though all other conditions for enterotoxin production were fulfilled. Gross and Vinton[8] observed that enterotoxin was not formed at 43° F. for two weeks in pork meats. To avoid hazard from growth of these bacteria, it is well to provide a safety margin by considering the incubation danger zone to be 50°

[4] "Bacterial Food Poisoning," 34 *Canadian Journal of Public Health* 97-111, 205-235 (1943).

[5] See footnote 2.

[6] L. B. Jensen, in 114 *Journal of the American Veterinary Medical Association* 63-65 (1944).

[7] M. J. Segalove and G. M. Dack, in 6 *Food Research* 127-133 (1941).

[8] C. E. Gross and C. Vinton, 12 *Food Research* 188-202 (1947).

F. to 120° F., especially in operating steam tables for food service. The *cumulative* effect of incubation at 80° F. for one to five hours, followed by refrigeration at each interval of 12 hours, will enhance toxin formation. This was found to be caused by increasing numbers of cells at each growth period (past the lag phase) which furnished greater numbers of cells to grow at the logarithmic phase and form toxin.

Not all foods or media are found to support growth of staphylococci, and some foods supporting growth do not contain enterotoxin.[9] Low-acid foods [10] may support growth and enterotoxin formation, but some foods do not become toxic.[11] The lag phase of growth is prolonged beginning at pH 5.8 and growth ceases at pH 4.4. Common salt in brine concentrations (ratio of salt to moisture) of 5 per cent to 7 per cent permits growth and toxin production, but the lag phase of growth is somewhat lengthened.

Salmonellae

The salmonellae were so named for Dr. D. E. Salmon, former Chief of the Bureau of Animal Industry, United States Department of Agriculture, who first described a member of this group in 1885. There has been a great deal of controversy on the role of salmonellae in food poisoning and food infection. Dr. G. M. Dack [12] states: "Perhaps no field is more confused than the one concerned with the role of the Salmonella organisms in food poisoning." The confusion has centered on supposed toxin formation by the group and dosage of cells necessary to produce symptoms of illness in humans. Adequate methods for isolation and identification of these bacteria were wanting until quite recently, although much remains to be done in quantitative determinations of these bacteria in various inocula.

Tests performed by Dr. G. M. Dack on 24 human volunteers, who were fed up to 11 ounces of cell-free filtrates and heat killed broth cultures of nine strains of salmonella, failed to produce any symptoms of illness. Verder and Sutton [13] also tested filtrates and heated suspensions of salmonella by feeding seven human volunteers, none of whom became ill.

[9] See footnote 3.
[10] M. Segalove, E. Davison and G. M. Dack, 8 *Food Research* 54-57 (1943); M. Surgalla and G. M. Dack, 10 *Food Research* 108-113 (1945).
[11] E. Davison and G. M. Dack, 7 *Food Research* 80 (1942).
[12] See footnote 3.
[13] A. S. Verder and C. Sutton, 53 *Journal of Infectious Diseases* 262-271 (1933).

There can be no doubt that salmonella food poisoning is actually an infection and not an intoxication from supposed toxic substances of growth.

The dosage or numbers of salmonellae necessary to elicit illness in humans has been studied by McCullough and Eisle,[14] who found illness resulted with *S. meleagridis* at 7.67 million cells and another strain required 24 millions cells. With *S. anatum*, the range was 587,000 and 860,000 levels for one strain and 44.5 million and 67.2 million levels for another. With *S. bareilly* and *S. newport*, the lowest dosage was 125,000 and 152,000, respectively. *S. derby* produced illness at the highest level fed—15,000,000 organisms, although five lower dosage levels were employed. *S. pullorum* was fed at eight dosage levels but 1.3 to ten billion organisms were required to produce illness.

The salmonellae are widespread in nature and have been found associated with man, mammals, birds, reptiles and insects. Their presence in dust, soil, water and unprotected foods is to be expected. E. O. Jordan [15] stated:

> . . . some investigators, especially German writers, regard them (Salmonella) as so widely distributed in nature that any attempt to control the spread of infection is like fighting windmills. According to this view, the bacilli occur commonly in our every day surroundings, and thence make their way rather frequently into a variety of food stuffs.

Many standard examinations of air samples from streets, rooms of buildings, vacuum-sweeper dust, and swabbings of surfaces in areas inhabited by animals and man frequently show salmonellae of the C group, as well as other serological groups. Human carriers, rodents and flies spread these bacteria. Wherever fecal coliform bacilli are found, salmonellae may be expected, and recent examinations again show this to be the case. We live in an environment where salmonellae may be present in sparse or moderately low numbers. The question arises then: Does one living cell of this group cause salmonellosis when ingested? The data for adults are known from the work of McCullough and Eisle cited above. If one, two or ten salmonella cells could cause food poisoning, it is apparent that very high morbidity rates of salmonellosis would be observed and documented in reportable areas.

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[14] N. B. McCullough and C. W. Eisle, 88 *Journal of Infectious Diseases* 278-289 (1951); 89 *Journal of Infectious Diseases* 209-213, 259-265; 66 *Journal of Immunology* 595-608 (1951).

[15] *Food Poisoning and Food-Borne Infection* (The University of Chicago Press, 1931), pp. 154-155.

Meats produced under the Federal Meat Inspection Service preclude sale of unsound or diseased tissues, and are processed under conditions provided for by the Meat Inspection Act and subsequent amendments. Dr. G. M. Dack states:

> The scarcity of Salmonella outbreaks from meat products in this country is probably a true measure of the effectiveness of our meat inspection. Our excellent federal meat inspection has been an example to municipalities which have to deal with small abattoirs furnishing meat that is consumed locally.

Streptococci

Streptococci of the alpha type, that is, able to oxidize red hemoglobin and myoglobin to the green choleglobins, have been found (as the causative organisms) in a few outbreaks of gastrointestinal irritation. These bacteria, usually classified as *Streptococcus faecalis* (Lancefield group D), grown on foods and laboratory media, have been fed to human volunteers. Toxins or toxic substances from growth are not formed. Culture filtrates and heat-killed cells in huge dosage do not give rise to symptoms of food poisoning. Our own human volunteer tests have shown that living cells when ingested give rise to mild symptoms of gastrointestinal irritation in most individuals, and the time of onset of symptoms ranges from six to 12 hours, with extremes of three to 18 hours. Not all *Streptococcus faecalis* strains are capable of causing illness. They grow in the range 60° F. to 113° F. and show salt tolerance. In the several outbreaks studied,[16] enormous numbers of cells were ingested with the foods. Dosage can determine the initial time for onset of illness. The symptoms include nausea, vomiting in some cases, colic and diarrhea, but are usually milder in nature than those caused by staphylococcal enterotoxin.

Some strains are killed at pasteurizing temperature, but a few strains require higher temperatures. The sources of *Str. faecalis* are usually intestinal contents of man, mammals and birds and, subsequently, soil, dust, water and foods and drink which become contaminated and serve as vectors. Most outbreaks investigated by us have been caused by eating poultry dressing which had been incubated and not adequately heated or cooked after stuffing into the body cavity of the fowl. Prevention of this type of food poisoning calls for proper refrigeration of the food, that is, keeping the food out of the incubation danger zone, and for adequate culinary heating of the food to destroy vegetative bacteria.

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[16] See footnote 3.

Clostridium Botulinum

Clostridium botulinum [17] is a spore-bearing anaerobic rod. There are five types of this organism, A, B, C, D and E, based upon the antigenicity of toxins, that is, serologically. The antitoxins for one type will not neutralize the toxins of another, although very large doses of type A or of type C antitoxin seem to exert a slight neutralizing power upon type B toxin.[18] The physiological action of the toxins seems identical, but the basis for type distinction can be obtained by antitoxin protection in susceptible laboratory animals (white mice and guinea pigs) and susceptibility of various animals and birds to the several toxins. For instance, mink are highly susceptible to small doses of type C toxin and resistant to huge doses of the other types of botulinum toxin.[19] Types C and D have not been reported to cause botulism in humans. Most outbreaks have been caused by types A and B, and a few by the exotoxin of the marine type E.

Large numbers of washed spores may be fed to animals without producing botulism and, undoubtedly, small numbers of these spores are ingested daily by man, since they are widespread in nature. World-wide examinations of soil samples have shown their ubiquity. The spores do not germinate and grow in the intestinal tract.

Many kinds of foods have been implicated in botulism, but *Cl. botulinum* will not grow in the presence of air. Acidities maintained at pH 4.4 will prevent germination of these spores and growth of their vegetative cells. The toxins are susceptible to heat. Dr. K. F. Meyer [20] found that type A toxin is destroyed at 80° C. (176° F.) within two to 18 minutes, and at 65° C. (149° F.) within ten to 85 minutes. Toxin of strains of type B required 15 minutes at 80° C. (176° F.) for nullification of toxicity, and toxin of type C required 30 minutes at 80° C. (176° F.). Others have found type C toxin destroyed in eight to 15 minutes at 80° C. (176° F.). Type A toxin has been crystallized and found to be made up of 19 amino acids with a molecular weight of about one million, but no clues to the extreme toxicity are at hand.

In humans, botulism is not regularly characterized by gastro-intestinal irritation. Nausea and vomiting may in some instances be

[17] Some bacteriologists designate the proteolytic varieties as *Cl. parabotulinum*. Type A and the American type B strains are proteolytic, but many European type B strains are not proteolytic.

[18] L. B. Jensen, 39 *Journal of Infectious Diseases* 413-423 (1926).

[19] R. O. Waagenaar, G. M. Dack and D. P. Mayer, 14 *American Journal of Veterinary Research* 479-483 (1953).

[20] 4 *Handb. d. path. Mikroorg*, 1261-1364 (1928).

caused by the degree of food spoilage and the amount of food eaten. Constipation is the rule. The symptoms are sharply contrasted to those observed in staphylococcal, streptococcal and salmonella types of food poisoning. *Botulinum* toxin is a neurotoxin and *botulinum* intoxication involves the central nervous system. In most cases the earliest symptom is fatigue associated with headache or dizziness. Double vision or diplopia occurs early from involvement of the extra-ocular muscles controlling the eyeball. Difficulty in swallowing and drooling also occur early. The temperature is normal or subnormal. Respiration is irregular and, if death occurs, respiratory failure is usually the cause. The mortality rate is very high (about 65 per cent in the United States). The disease is fortunately rare in occurrence; 462 outbreaks have occurred in this country during the years 1899 to 1947.

In 85 per cent of the cases, recorded symptoms of botulism occurred within 48 hours after ingestion of the toxin. The range is 12 hours to four days, usually 24 hours. The dosage determines to some extent the time of onset.

Toxin is not formed at temperatures of 41° F. or lower, and Tanner, Beamer and Rickher stated that foods, when kept below 50° F., will remain safe for a considerable length of time.[21] Type E toxin can form at 43° F., but is very heat labile, and is destroyed far below pasteurization temperatures and times. It is ordinarily of marine origin. A few cases have been reported in British Columbia, but most of the known outbreaks occur in Southwest Russia.

Care of Foods—Prevention of Common Staphylococcal Outbreaks

Dr. F. W. Tanner [22] states:

> The problem of food poisoning is of far less importance than some are prone to believe. Billions of pounds of foods are processed and distributed in the United States without causing illness.

The National Sanitation Foundation maintains that "sanitation is a way of life which must come from within people."

As a further safeguard against food-poisoning hazards, the foods should be cooked carefully according to instructions so that these bacteria of chance inoculation are destroyed. As an example, a ham should be cooked so that the inside reaches a temperature of at least

[21] F. W. Tanner, P. R. Beamer and C. J. Rickher, 5 *Food Research* 323-333 (1940).

[22] *Microbiology of Foods* (Champaign, Illinois, Garrard Press, 1944) (Preface).

162° F. We must apply these temperatures to the meat just as the dairy operator must pasteurize milk and cream to safeguard them. In this connection, we have seen mess halls and galleys where bone-in, smoked hams, for instance, were held at temperatures of 36 to 40° F. in the meat coolers and, while there, sawed raw (beginning at stifle joint) on circular and band saws into slices, the slices placed in pans in the cooler, then taken to the steam pressure cookers and cooked at eight to ten pounds' pressure for about 30 minutes. The ham slices were then served and were never held in the incubation zone for over three hours. It is apparent that this method is preferable to the cooking and then slicing methods sometimes presumably employed in institutional-type feeding. So far as the writer knows, no food poisoning due to ham has arisen in kitchens and galleys where the kitchen personnel cut or sawed the hams into slices and then cooked them as described above. The inference is obvious. Contamination of adequately cooked hams occurs during the slicing operations and after, and when the slices are held in the incubation zone for over four hours, enterotoxin can form if poisonous staphylococci are present.

No one can tell whether or not a food is likely to make you ill (if you eat it) by the taste, smell, feel or appearance. Many of the staphylococcus food-poisoning outbreaks have been caused by foods which show no definite off-conditions. You must know how the food was handled to know that your meal is safe to serve.

The following examples will illustrate particular product hazards and methods of avoiding them:

(1) When turkeys or other fowl are prepared, do not permit the stuffing or dressing to be held at a temperature above 50° F. or below 130° F. for a longer period than four hours. Refrigerate the food and warm up the food to 165° F. or higher for 30 minutes before serving again. The dressing, gravy and scraps are excellent bacterial culture mediums.

(2) When sandwiches are prepared, never allow the bread or filler to remain at danger temperatures (50° F. to 130° F.) for a longer period than four hours. The dangerous bacteria (staphylococci) grow well in most fillers, and especially well in moistened bread. It has been shown in some large outbreaks that the bread in the incubated sandwiches became poisonous as well as the sandwich filler. Never keep the slices of bread moist with a damp cloth as is so frequently done.

If the filler is ham or cured or smoked tongue, fried egg, egg salad, fish, sausage, etc., special care must be exercised so that the filler is freshly prepared from materials that have not been in the incubation zone longer than a few minutes. You must realize that if, let us say, ham has been sliced and held on platters for three hours in the "incubation zone," the life of the ham in a sandwich should only be one additional hour when held in the incubation zone before serving.

(3) Dehydrated food products, such as dried eggs, dehydrated beef and pork, dried milk, etc., do not undergo bacterial spoilage if the moisture content is below 10 per cent. When these products are reconstituted by the addition of water, it must be remembered that bacterial growth begins after 30 per cent of water is added. It becomes important, therefore, that these products be protected from inoculation at all times and from the incubation zone of temperature during and after reconstitution. In general, it may be said that these dehydrated products should not be held in the incubation zone of temperature more than three hours, after the water is added for reconstitution, before the product is consumed. If a greater time is required, the product should be refrigerated to a temperature under 50° F. or heated to a temperature of over 130° F. until ready for consumption.

(4) Cooked hams, if placed on steam tables, must be kept at 130° F. or above. Cooked hams must not be held for a period longer than four hours in the incubation range of temperature. It must be remembered that this time within the incubating temperature range is in a sense accumulative, so that if the product is refrigerated at intervals, the total time of the various periods within the incubation zone should not be more than four hours.

(5) Hold-over soups are frequent offenders. Experiments have shown that if soups must be held over, the liquid must be cooled rapidly to 50° F. and then held in a 36-38° F. cooler not longer than three days before use. At 42° F. these stocks can spoil in less than 48 hours from growth of many types of saprophytic bacteria.

Keeping Food Safe

(1) Avoid contamination from likely sources of staphylococci: People with boils should not handle foods. People who sneeze or cough often should not handle foods. Do not sneeze or cough in the places where food is prepared and served. People with sores or infected cuts on fingers and hands should not handle foods.

(Continued on page 644)

Significant Comments

By THOMAS W. CHRISTOPHER

Decisions

Negligence and Privity.—(1) A chemical company sold empty barrels contaminated with a deadly poison to a manufacturer of animal feeds with knowledge that the barrels would be used for livestock feed. The plaintiff bought feed in the barrels from the feed manufacturer and fed it to his cattle, and the cattle died. The chemical company was held liable.[1]

There was no privity of contract between the plaintiff and the chemical company [2] and there was no negligence in the original placing of the poison in the barrels. The negligence was in leaving the poison therein, knowing the barrels were to be used for feed and that injury might result. The court wrote:

> In principle, a manufacturer or other person owning or controlling a thing that is dangerous in its nature or is in a dangerous condition, either to his knowledge or as a result of his want of reasonable care in manufacture or inspection, who deals with or disposes of that thing in a way that he foresees or in the exercise of reasonable care ought to foresee will probably carry that thing into contact with some person, known or unknown, who will probably be ignorant of the danger, owes a legal duty to every such person to use reasonable care to prevent injury to him.

The leading case on this principle doubtless is *Palsgraf v. Long Island Railroad Company.*[3] There, Judge Cardozo, for the majority, held that negligence in such a situation must be based on the foreseeability of injury to the person harmed, and thus that there is no duty

[1] *Colvin v. John Powell & Company*, CCH Food Drug Cosmetic Law Reports ¶ 22,463, 77 N. W. (2d) 900 (Neb., 1956).

[2] See *MacPherson v. Buick Motor Company*, 217 N. Y. 382, 111 N. E. 1050 (1916).

[3] 248 N. Y. 339, 162 N. E. 99 (1928).

to the unforeseeable party.[4] In the present case, the plaintiff was a foreseeable party, and so there is no violence to the *Palsgraf* rule.

(2) A plaintiff bought animal feed from a retailer. As a result of poisonous anthrax bacilli in the bone meal, the buyer's cattle were killed, and he brought suit against the manufacturer for negligence. On general demurrer, the defendant contended that since the case was based on negligence, there could be no recovery against the manufacturer. The argument was that a manufacturer, though negligent, and though the feed killed the animals, nevertheless is not liable to such purchaser. The court rejected this contention, saying:

> . . . if a manufacturer negligently in the manufacture of feed to be sold to the public for the purpose of being fed to animals of the purchaser puts therein substances . . . that will kill or injure the animals, the manufacturer . . . is liable.

The court said further:

> . . . the trend of cases decided in this State appears to be to allow recovery on the part of a consumer or user of products, if through a failure to exercise ordinary care on the part of a manufacturer or someone not in privity with the user, the product is imperfect, defective, or not as represented when placed on the market, and damage to the consumer or user is proximately caused thereby.[5]

The manufacturer here confuses tort and contract. The common law rule requires privity in a warranty action, a rule still followed in many states. But in recent decades, courts have generally held that privity is not necessary in negligence actions.[6] Duty is the test here. If injury can be foreseen or if there is a possibility of injury to a foreseeable person, the actor is liable.[7]

Regulatory Power.—The Florida Citrus Commission, by regulation, prohibited the addition of sugar (or any other additive) to "chilled orange juice." Such additive was permitted in "canned orange juice." A plaintiff contended that chilled orange juice meets the statutory definition of canned orange juice (permitting sugar), and is not a new product. The court upheld the regulation, saying that customers considered the chilled product to be fresh juice, and that different regulations were permissible. It also found that this regulation, of itself, was reasonable in that it protected the consumer against fraud and deception, and in that it protected the Florida citrus industry from unfair competition.[8]

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[4] Restatement of Torts, Sec. 281, Com. C, adopts this view. The dissent in the case thought that there was a duty to all. See Prosser, "*Palsgraf* Revisited," 52 *Michigan Law Review* 1 (1953).

[5] *G. Bernd Company v. Rahn*, CCH Food Drug Cosmetic Law Reports ¶ 22,466 (Ga. Ct. of App., 1956).

[6] See footnote 2.

[7] See Prosser, *Law of Torts* (1955), p. 498.

[8] *Florida Citrus Commissioner v. Golden Gift, Inc.*, CCH Food Drug Cosmetic Law Reports ¶ 85,167 (Fla., 1956).

Inspection.—The defendants shipped misbranded drugs to a purchaser, and an inspection was made while the goods were in the possession of the latter and with his permission. The inspection took place prior to the compulsory-inspection amendment.

The defendants contended that since they did not give permission to inspect, they cannot be held liable under the Fourth Amendment—that only the person who gave permission is liable.

The court rejected this contention, saying that "a person cannot complain under the Fourth Amendment when a third person consents to a search of property belonging to the defendant but in the possession of the third person." It added that, in the present case, the property did not belong to the defendants, but to the purchasers.[9]

While this case deals with the old "permission" inspections, the principle stated is important under the present inspection statute.

BACTERIAL FOOD POISONING—Continued from page 641

(2) Cook all foods thoroughly.

(3) Avoid the incubation zone. To be safe, always hold foods at temperatures below 50° F. or above 130° F.

Lois C. Black and Martha N. Lewis[23] studied the effect on bacterial growth of various methods of cooling cooked foods and concluded:

> Internal cooling of hams, chickens, broths, and soft custards cooked in large quantity was hastened by refrigeration immediately after cooking. These results indicated that foods should be refrigerated either immediately after cooking or should be cooled at room temperature for ¼ to ½ hr. and then refrigerated, as the rate of heat loss during this initial short cooling period was essentially the same in or out of the refrigerator.

Precise information on the subjects of storage and handling of meats, and rules for maintaining maximum safe holding periods for all types of meat foods are given elsewhere.[24] **[The End]**

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[9] *U. S. v. El Rancho Adolphus Products, Inc.*, CCH Food Drug Cosmetic Law Reports ¶ 7361, 140 F. Supp. 645 (DC Pa., 1956).

[23] 24 *Journal of the American Dietetic Association* 399-404 (1948).

[24] L. B. Jensen, *Meat and Meat Foods* (New York, Ronald Press, 1949), Ch. 12, and *Microbiology of Meats* (Champaign, Illinois, Garrard Press, 3d Ed., 1954).

THE INDEX TO THIS VOLUME HAS BEEN REMOVED FROM THIS POSITION AND PLACED AT THE BEGINNING OF THE FILM FOR THE CONVENIENCE OF READERS

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